## **EXHIBIT C**



## Life Care Plan

#### **Rose Hills**

DOB: 08/12/81

Date of Report: 07/14/19

MD Certified Life Care Planner

4201 Bee Caves Road Suite C-213 West Lake Hills, TX 78746

512-960-4717

Total Cost of LCP without Occipital Nerve Blocks: \$713,802

Total Cost of LCP with Occipital Nerve Blocks: \$1,261,770



Client: Rose Hills Date of Report: 07/14/19

DOI: 10/13/16

Life Expectancy: 48 years.

Date of Evaluation: 7/11/19

Location of Evaluation:

4201 Bee Caves Rd, Suite C-213, West Lake Hills, TX 78746

Report completed by: Dr. Hector Miranda-Grajales, MD, CLCP

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#### Introduction

A life care plan is a dynamic document based upon published standards of practice, comprehensive assessment, data analysis, and research, which provides an organized, concise plan for current and future needs with associated costs for individuals who have experienced catastrophic injury or have chronic health care needs. (International Academy of Life Care Planners, 2003. Established during the 2000 Life Care Planning Summit). A life care plan is designed, among many things, to help reduce medical complications and provide the best possible care for the unique needs of the particular patient involved.

The opinions, diagnoses, and conclusions mentioned in this report are based within a reasonable degree of rehabilitation and medical certainty. These opinions are based on my clinical experience as well as my training in physical medicine and rehabilitation, pain management, and life care planning. They are also based on the history provided, records reviewed, and examination findings. I reserve the right to modify my opinion should new information be made available to me.

#### Independent Medical Examination (IME) Report For Life Care Plan

In regards to: Rose Hills (examinee and patient)

Date of Birth: 8/12/81

Date of Loss: 10/13/16

Examiner: Hector Miranda-Grajales, MD

Specialty: Physical Medicine & Rehabilitation/Interventional Pain Management/Life Care

Planner

Date of IME: 7/11/19

#### **Questionnaire**

Home address: 1814 Buckskin Trl, Temple, TX 76502

Cell phone number: 254-421-0014

Age: 37

Race: Hispanic

Sex: Female

Dominant hand: Right

Work history: Hair stylist.

Prior accidents: She was involved in a car accident in 1999; she did not have chronic headaches or pain after that accident; she did not treat with a chiropractor, physical therapist, pain doctor, or surgeon after that accident. She was involved in another accident in 2000 or 2001. She was taken to the hospital by ambulance and was discharged home the same day. She developed lower back and right hip pain that resolved with chiropractic care. She did not have aggravated headaches after that accident. She did not treat with physical therapy, pain management, or surgeon after that accident. In 2002 she was assaulted and was punched in the nose and went to the ER. She did not have aggravated headaches, neck or back pain after that assault. She has not been assaulted, injured in a car accident, or in another slip and fall incident since the slip and fall of 10/13/16.

Has the patient ever had any disability prior to the accident in question?

Can the patient drive a car? Yes.

Sleeping habits: She wakes up at night with neck pain and headaches.

Social Activities: She reports with Emgality injections she can function more.

Activities of Daily Living: She is independent in ADLs.

#### Disclaimer

The examinee was informed that today's examination was to evaluate specific conditions pertinent to the accident in question; hence, information provided would not be confidential. Prior to the physical examination the patient was instructed not to perform any maneuver that might cause injury or exacerbation of symptoms, and to advise the examiner to avoid or immediately abort any such test.

#### **Records Summary**

Date	Provider	Note Type	Summary
10/13/16	•	Incident report	Mrs. Hills fell at the parking lot.
10/13/16	Baylor Scott & White	Progress note	She treated for whiplash injury, shoulder pain, neck pain.
10/17/16	Baylor Scott & White	Progress note	She treated for neck and wrist pain.
10/18/16	Baylor Scott & White	Progress note	She treated for neck and left wrist pain.
10/21/2016 - 1/9/17	Comprehensive Injury Treatment Services	Billing records	As of 10/21/16 she reported headaches.
10/31/2016 - 8/14/17	Baylor Scott & White	Progress note	She treated for neck pain and headaches.
11/14/2016 - 1/6/17	PT	Progress note	She treated for neck pain and headaches.
2/24/17	Pain Specialists of Austin	Progress note	She treated for pain in: neck, left shoulder, and left arm. She was diagnosed with cervical radiculopathy and a cervical ESI was recommended.
4/8/2019 - 11/29/17	Baylor Scott & White	Progress note	Mrs. Hills treated for post-traumatic headaches and neck pain. Her cervical MRI showed disc protrusions in: C5-6, C7-T1, T1-2.

#### **Summary**

HPI: Mrs. Hills is a 37 y/o woman who was injured in a slip and fall accident on 10/13/16 at Sam's Club parking lot. She did not hit her head. She landed on her hands and knees. She did not hurt at the time of the fall. She went home that day and when she woke up she "could not move her neck." She then went to the ER the same day of the slip and fall due to neck pain and headaches. She eventually developed numbness in her left 4th and 5th digits that persists to today. She treated with a chiropractor, but this treatment did not provide long term relief. She treated at Pain Specialists of Austin. Her pain doctor recommended injections of her neck. However, she has glaucoma and her ophthalmologist advised against doing any kind of steroid injections "because I can go blind." She did not proceed with cervical steroid injections.

Note, she was on gabapentin, but this did not help. She had an adverse reaction to Lyrica, she was "seeing things" while on that medication. Robaxin did not help much either. She is treating with Dr. Cabret for her headaches. She started Emgality injections for her migraines. She had a

history of headaches prior to the fall, since her mid 20s, but those headaches were resolved with over the counter medications and were not nearly as frequent and severe as they have become since the fall of 10/13/16.

Her post-traumatic headaches started after the fall of 10/13/16. They are constant; intensity: 6-9/10; her room is "blacked out" because bright lights make her headaches worse (also worsened with noise, and certain smells); she reports that Emgality, a prophylactic headache medication, helps bring down her headaches to 6/10. Without the Emgality, she would throw up from the nausea, and would be dizzy. Prior to taking Emgality she was taking anti-emetic medications daily, and now she only takes them once a week. She cannot take triptans because they make her drowsy. She takes Nortriptyline to sleep better. She takes dihydroergotamine 4mg/mL sprays for severe headaches at least twice a week. The headaches are throbbing, stabbing, shooting, tension-like. They're located on the back of her head and shoot to the front.

Her neck pain is constant; quality: throbbing, burning; it shoots down the left arm; intensity: 5-9/10; not associated with spasms; worsened with neck motion.

Review of Systems: as above.

Medications: Dihydroergotamine 4mg/mL sprays twice a week, Emgality 120mg/ml once a month, Reglan 10mg once a week, birth control, eye drops for glaucoma, Nortriptyline 40mg at night.

PMH: Glaucoma.

PSH: Tubal ligation.

Allergies: NKDA.

FH: Mother: diabetic, hypertension (alive); father: alive, has hypertension.

Social History: She does not smoke cigarettes or drink alcohol.

Physical Exam:

Constitutional: Patient is A & O X 3, normal in appearance, attention to hygiene and body habitus, in no apparent distress and coherent and cooperative.

Eyes: Examination of eyes reveals normal eyelids and conjunctivae; normal irises.

ENT/Mouth: Normal external ears and nose; normal hearing

Cardiovascular: no edema in extremities; palpable pedal pulses

Respiratory: normal respiratory effort

MSK:

ROM: Limited cervical ROM on extension and rotation due to pain.

Palpation: Tenderness to palpation in cervical paraspinal muscles.

Strength: 5/5 in upper and lower extremities.

Sensation: Intact to light touch in upper and lower extremities.

DTRs: 2+ in upper and lower extremities.

Neuro: Cranial nerves intact.

#### **Analysis Of Findings**

<u>Diagnoses:</u> The patient suffers from the following conditions, which are causally related to the slip and fall of 10/13/16:

- Post-traumatic headaches.
- 2. Post-traumatic cervical radiculopathy.
- 3. Post-traumatic disc herniations in: C5-6, C7-T1, T1-2.

<u>Clinical Status:</u> It is within a reasonable degree of medical certainty that the patient's impairments are permanent.

#### **Itemized Records**

- 1. Pain Specialists of Austin Records
- 2. BSW bills
- 3. BSW records
- 4. BSW Supplement
- 5. CVS meds
- 6. HEB pt expense
- 7. Incident report
- 8. Plaintiff's First Amended Comp
- 9. Plaintiff's R.26 Initial Disclosures
- 10. Pltf's First Amended Disclosures
- 11. Rose Hills deposition
- 12. Walmart meds 2
- 13. Walmart meds

#### **Cost Sources**

- 1. Fair Health Online database was used to calculate medical services. The rates for care and services are from the claimant's geographical area.
- 2. Source for medications: Goodrx.com

Geozip: 76502

Year of benchmarks FAIR HEALTH: April 2019

#### Future care without ONBs

ltem	Frequency	CPT	Rate
Neurology	3x per year	99214	\$ 212
*Dihydroergotamine	4mg/mL sprays twice a week	-	\$5,190 per year.
Emgality 120mg/pen	1 per month	-	\$8,280 per year.
Reglan	10mg once a week	-	\$4 per year.
Nortriptyline	40mg qhs	-	\$207 per year.
Cervical MRI	1x every 5 years	72141	\$ 2,954

<sup>\*</sup>One spray has 0.5mg; it is sprayed twice in each nostril (2mg per use). 1 vial has 3.5 mL (14 mg per vial). At twice a week, she is using 4mg/week or 208 mg/year (52\*4=208). She will need 15 (208/14=15) vials per year. \$346 per vial. \$5,190 per year.

#### Future care with ONBs

Item	Frequency	CPT	Rate
Neurology	3x per year	99214	\$ 212
Bilateral greater and lesser occipital nerve blocks (ONB)	2x per year	64405x2, 64450x2	\$ 5,708
Dihydroergotamine	4mg/mL sprays twice a week	-	\$5,190 per year.
Emgality 120mg/pen	1 per month	-	\$8,280 per year.
Reglan	10mg once a week	-	\$4 per year.
Nortriptyline	40mg qhs	-	\$207 per year.
Cervical MRI	1x every 5 years	72141	\$ 2,954

Item	CPT	Rate
Greater ONB	64405	\$1,708
Lesser ONB	64450	\$1,146

Hector A. Miranda-Grajales, M.D., C.L.C.P.
Diplomate of American Board of Physical Medicine and Rehabilitation
Board Certified Pain Management Specialist
Board Certified in Brain Injury Medicine
Certified Life Care Planner



**Life Care Plan Tables** 

A life expectancy was obtained from the National Vital Statistics Report Volume 67. Number 7, November 13, 2018. Table 12.
According to this source, Rose Hills's life expectancy is 48 years.
The expected age of death is 85 years old.

DOB: 8/12/1981 AGE: 37 RACE: Hispanic

Client Name: Rose Hills Date of Injury: 10/13/2016 Gender: Female

#### **Projected Evaluations**

Primary Disability: Post-traumatic: headaches, cervical radiculopathy.

Date of Preparation: 7/14/19

-	Item	Freque Units	Need Every	Puration of	Average Cost	Average inual Cost	Years of Duration	Averag	e Total Cost	Age At Start	Age At End	Comment
ı	LCP	1	X	48	\$ -	\$ -	48	\$	-	37	85	
ı	Totals				\$ -	\$ -		\$	-			

Projected Evaluations Average Unit Cost Total: \$ Projected Evaluations Average Annual Cost Total: \$
Projected Evaluations Average Cost Total: \$

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#### Projected Treatment - without ONBs

Primary Disability: Post-traumatic: headaches, cervical radiculopathy.

DOB: 8/12/1981 AGE: 37

Client Name: Rose Hills Date of Injury: 10/13/16 Date of Preparation: 07/14/19

The expected age of death is 85 years old.

Ltent	Frequ	ency and	Duration	Aver	age		Average	Years of		age Total Cost	Age At	Age At	Cited age of deam is 65 years old.
	Units		# Years	Co	st	A	inual Cost	Duration	AYE	age 10m Cost	Start	End	Comment
Neurology	3	Х	1	\$ 21	2.00	\$	636,00	48	\$	30,528.00	37	85	
Dihydroergotamine	I	Х	1	\$ 5,19	00.00	\$	5,190.00	48	\$	249,120.00	37	85	
Emgality	1	X	1	\$ 8,28	00.0	\$	8,280.00	48	\$	397,440.00	37	85	
Reglan	1	X	1	\$	4.00	\$	4.00	48	\$	192.00	37	85	
Nortriptyline	1	X	1	\$ 20	7.00	\$	207.00	48	\$	9,936.00	37	85	
Cervical MRI	1	X	5	\$ 2,95	4.00	\$	590.80	48	\$	26,586.00	37	85	
Totals				\$ 16,84	7.00	\$	14,907.80		\$	713,802.00			

Projected Treatment - without ONBs Average Unit Cost Total: \$ 16.847.00 Projected Treatment - without ONBs Average Annual Cost Total: \$
Projected Treatment - without ONBs Average Cost Total: \$ 14,907.80 713,802.00

#### Projected Treatment - with ONBs

Primary Disability: Post-traumatic: headaches, cervical radiculopathy.

DOB: 8/12/1981 AGE: 37

Client Name: Rose Hills Date of Injury: 10/13/16 Date of Preparation: 07/14/19

									The expe	ected age of death is 85 years old.
Item	Frequ	of Nee	Duration d	Average	Average	Years of	Average Total Cost		Age At	Comment
	Units	Every	#Years	Cost	Annual Cost	Duration		Start	End	- Committee
Neurology	3	X	1	\$ 212.00	\$ 636.00	48	\$ 30,528,00	37	85	
ONBs	2	X	I	\$ 5,708.00	\$ 11,416.00	48	\$ 547,968.00	37	85	
Dihydroergotamine	1	X	1	\$ 5,190.00	\$ 5,190.00	48	\$ 249,120.00	37	85	
Emgality	1	X	1	\$ 8,280.00	\$ 8,280.00	48	\$ 397,440.00	37	85	
Reglan	1	X	1	\$ 4.00	\$ 4.00	48	\$ 192.00	37	85	
Nortriptyline	1	X	1	\$ 207.00	\$ 207.00	48	\$ 9,936.00	37	85	
Cervical MRI	1	Х	5	\$ 2,954.00	\$ 590.80	48	\$ 26,586.00	37	85	
Totals				\$22,555.00	\$ 26,323.80		\$ 1.261.770.00			

Projected Projected Treatment - with ONBs Average Unit Cost Total: \$ 22,555.00 Projected Projected Treatment - with ONBs Average Annual Cost Total: \$ 26,323.80 Projected Projected Treatment - with ONBs Average Cost Total: \$ 1,261,770.00

# CURRICULUM VITAE HÉCTOR A. MIRANDA-GRAJALES, MD, FAAPM&R, CLCP

#### March 2019

4201 Bee Caves Rd., Suite C-213 West Lake Hills, TX 78746-6458

email:

hmirandamd@mdclcp.net hmirandamd@medinjury.net

Office: (512) 960-4717 Fax: 855-868-9882

#### **LANGUAGES SPOKEN**

- English
- Spanish

#### **MEDICAL LICENSES:**

Florida: ME107880

Texas: Q4469

New York: 262463-1California: C149232

#### **CERTIFICATIONS**

- Board Certified in Brain Injury Medicine
  - o December 1, 2016 December 31, 2026
  - Certificate Number: 385
- Certified Life Care Planner (CLCP)
  - o September 2015
  - Certified by the University of Florida, College of Public Health & Human Professions, Department of Behavioral Science & Community Health
- Board Certified in Pain Medicine
  - o August 18, 2012 December 31, 2022
  - Certificate Number: 1521
- Diplomate of American Board Physical Medicine and Rehabilitation
   7/1/2012 12/31/2022

o Certificate Number: 10537

#### PROFESSIONAL EXPERIENCE

September 3, 2013 –

- Founded Medical Injury Rehabilitation Specialists, LLC
  - Medical Director and interventional pain management physician of this practice
    - 4201 Bee Caves Road, Suite C-213, West Lake Hills, TX 78746
    - 4611 NW 53rd Avenue, Gainesville, FL 32653
    - 404 Hall of Fame Drive, Lake City, FL 32055
- August 27, 2012 August 26, 2013
  - Interventional pain management physician at the Institute of Pain Management
    - 1325 San Marco Blvd. Suite 4A, Jacksonville, FL, 32207;
       tel: 904- 306- 9860 fax: 904-306-9864; Business address:
       PO Box 57970 Jacksonville, FL 32241-7970
    - 4243 Sunbeam Rd., Jacksonville, FL, 32207; tel: 904-264-5661
    - 1210 Kingsley Ave., Orange Park, FL 32073; tel: 904-264-5661

#### **EDUCATION**

August 3, 2003 – June 15, 2007 University of Puerto Rico School of Medicine, Rio Piedras, Puerto Rico.

- o **M.D**.
- o Graduation June 15, 2007.
- o Graduated magna cum laude.

August 16,1999- February 16, 2003 University of Puerto Rico, Rio Piedras.

- B.S. General Sciences.
- o Graduated February 16, 2003.
- o Graduated magna cum laude.

#### **POSTGRADUATE TRAINING**

July 1, 2011-June 30, 2012

 Fellowship training in Anesthesia ACGME accredited Pain Management at Beth Israel Medical Center in New York City, NY.

July 1, 2008-June 30, 2011

 Residency training in Physical Medicine and Rehabilitation atthe University of Miami Miller School of Medicine.

July 1, 2007- June 30, 2008

 Internship in Internal Medicine at the Veterans Affairs Medical Center in San Juan, Puerto Rico.

#### HONORS/AWARDS/ACHIEVEMENTS

#### Residency

April 23, 2010

Named Chief Resident of PM&R residency program.

#### Undergraduate

2002-03

 Who's who among students in United States colleges and universities.

1999-03

- o Dean's List.
- o Honor Roll student at University of Puerto Rico, Rio Piedras.

#### **POSTERS & PUBLICATIONS**

2013

 Miranda-Grajales H., Hao J, Cruciani R. False Sense of Safety by Daily QTc Interval Monitoring During Methadone IVPCA Titration in a Patient with Chronic Pain. *Journal of Pain Research*; May 2013;6 375-378.

#### PROFESSIONAL ASSOCIATION MEMBERSHIPS

2015

- Member of American Medical Association
- Member of Texas Medical Association
- Member of American Academy of Physical Medicine & Rehabilitation
- Member of the International Association of Rehabilitation Professionals

Journal of Pain Research

Dovepress



CASE REPORT

# False sense of safety by daily QTc interval monitoring during methadone IVPCA titration in a patient with chronic pain

Hector Miranda-Grajales Joy Hao Ricardo A Cruciani

Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, New York, NY, USA Abstract: It has been proposed that some deaths attributed to methadone are related to prolongation of the QTc interval; however, there are no clear recommendations on electrocardiogram (ECG) monitoring in patients undergoing intravenous methadone infusion. This is a report on a patient receiving methadone intravenous patient-controlled analgesia titration for the treatment of chronic pain. Initially, her daily ECGs showed QTc intervals within normal limits; however, she experienced a rapid increase in QTc interval from 317 ms to 784 ms within a 24-hour period after methadone had been discontinued for excessive sedation. QTc interval greater than 500 ms is considered to be high risk for the fatal arrhythmia Torsades de Pointes. Daily ECGs did not detect a gradual increase in the QTc interval that would have alerted the medical staff of the need to decrease or stop the methadone before reaching a prolonged QTc interval associated with cardiotoxicity. In selected cases where aggressive methadone titration is required, more intensive monitoring, such as telemetry or ECG determinations every 12 hours, might help detect changes in QTc interval duration that might otherwise be missed by daily ECG determinations.

Keywords: methadone, QTc prolongation, opioids, opioid side effects, IVPCA methadone

#### **Background**

The use of methadone for the management of chronic pain has increased in the last decade, as has the number of the deaths attributed to its use. Methadone is a chiral mixture with a variable metabolization rate² that contributes to its unpredictable half-life (ranging between 15 and 150 hours), which can lead to drug accumulation and potential cardiac toxicity. Methadone and other opioids, including oxycodone, can block delayed potassium rectifying currents ( $I_{xx}$ ), thus interfering with the repolarization of the conductive tissue of the heart and predisposing to Torsade de Pointes (TdP), a fatal ventricular arrhythmia. On electrocardiogram (ECG), prolonged depolarization manifests as QTc interval prolongation. An acceptable QTc interval upper limit has been proposed to be 430 and 450 ms for males and females, respectively, while values beyond 500 ms are considered to be high risk for TdP irrespective of sex.

Although the use of intravenous (IV) methadone in the terminally ill population is considered to be safe,<sup>7</sup> and the QTc prolongation reported by Kornick et al was attributed to the preservative chlorobutanol,<sup>8</sup> many reports suggest that methadone itself may prolong the QTc interval in a dose-dependent manner.<sup>4</sup> Furthermore, coadministration of certain medications may increase the risk of cardiotoxicity, for example, drugs that have the potential to prolong the QTc interval,<sup>9</sup> such as certain antibiotics or antiarrhythmic agents, or drugs that may compete with methadone as substrates for the cytochrome P450 isoenzymes 3A4, 2D6, and 2B6,<sup>10</sup> such as certain antidepressants, resulting in

Correspondence: Ricardo A Cruciani 10 Union Square East, Suite 2Q-2R, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, New York, NY 10003, USA Tel +! 212 844 1390 Fax +! 212 844 6962 Email rcrucian@chpnet.org elevated methadone plasma levels. To address the risk of cardiotoxicity, some authors have advocated serial ECGs to monitor the QTc interval duration, <sup>11</sup> but the recommendations on frequency of monitoring and medication dose at which the ECG should be done are controversial <sup>12</sup> and range from "ECG is never necessary" to perform ECG "in every patient." <sup>13</sup>

#### Objective

To promote awareness that daily ECG monitoring during IV patient-controlled analgesia (PCA) with methadone may not be sufficient to anticipate a rapid prolongation of the QTc interval.

#### Methods and findings

The patient was a 50-year-old woman with chronic abdominal pain for over 10 years due to lupus vasculitis who during hospitalization for opioid rotation, experienced QTc prolongation beyond 500 ms during rapid IV methadone titration in less than 24 hours. The patient's pain had not been managed to satisfaction as an outpatient, and admission for IV opioid titration was recommended. At the time of admission to the Pain Service Inpatient Unit, Beth Israel Medical Center, New York, NY, USA, the patient's medications included morphine sulfate 150 mg intramuscular (IM) every 4 hours and meperidine 75 mg IM every 8 hours, and her pain score was 10/10. During hospitalization, the patient underwent trials with intravenous patient controlled analgesia (IVPCA) hydromorphone, morphine, and fentanyl, which did not alleviate the pain or cause significant side effects and had to be discontinued. Afterwards, the patient received IV methydlprednisolone and ketamine infusion, and both were ineffective. After a baseline ECG that showed a QTc interval of 449 ms, an IVPCA methadone trial was initiated. The 12-lead ECG was obtained with a MAC 5000 machine (GE Medical Systems, Milwaukee, WI, USA). The QT interval was measured manually by a board-certified cardiologist. The interval was corrected for heart rate using the Bazett formula;6

#### QTc = QT/Sqrt [RR].

QTc prolongation was defined as intervals longer than 430 ms for males and 450 ms for females. <sup>14</sup> During the first 7 days of methadone IVPCA titration, the QTc interval duration ranged from 416 to 449 ms (Table 1). On the morning of day 8, the QTc interval was 317 ms (Table 1). That night, due to excessive sedation, the IVPCA methadone was discontinued, so the patient received only 184 mg during the 24-hour period. During this episode, the patient was easily aroused; oriented to self, time, and space; had stable vital signs (BP

134/82; HR 62; RR 12); and had no evidence of arrhythmia (although an ECG was not done). The next morning, a repeat ECG showed a QTc interval of 784 ms (12 hours after the methadone IVPCA had been discontinued). At that point, the sedation was resolved, there was no evidence of withdrawal symptoms, and the electrolytes were within the normal range (K+4.3, Ca2+9.3, Mg2+2.0, aspartate aminotransferase (ALT) 17, alanine aminotransferase (AST) 16 for a reference range of 3.7-5.2 mEq/L, 8.5-10.9 mg/dL, 1.7-2.2 mg/dL, 8-37 IU/L, and 10-34 IU/L respectively). The patient remained on nortriptilyne 25 mg in the morning and afternoon and 50 at bed time (plasma level of 81 for a therapeutic range of 70-170 ng/mL), and baclofen 10 mg every 8 hours that she had been taking at the same dose for several months before this admission. It is worth noting that no new medications that could prolong the QTc interval or interfere with methadone metabolism were initiated at this admission, (for a list of medications that can prolong the QTc interval, visit http:// www.torsades.org). Twenty-four hours later, the QTc interval duration was 476 ms, and the patient reported a pain score of 8/10. At this time, methadone was resumed as an oral formulation at half the dose of that before discontinuation (30 mg three times a day), which is a dose that had not caused significant QTc interval prolongation a few days earlier. In addition, the patient received hydromorphone 8-16 mg IV every 3 hours as needed to provide additional pain relief and to control withdrawal symptoms. This combination of medications provided inadequate pain relief, as the patient reported pain scores ranging from 6/10 to 10/10.

On day 15, in view of the poor response obtained with IV and oral opioids (the patient continued to report pain scores of 10/10), methadone was discontinued, and a trial of neuroaxial analgesia that included hydromorphone, bupivacaine, clonidine, baclofen, and midazolam was conducted. At day 21, the patient continued reporting pain scores that ranged between 8/10 and 10/10, and the neuroaxial analgesia trial was discontinued. At this point, oral methadone was titrated, up to 30 mg four times a day, and the patient also received transdermal fentanyl 300 µg/hour every 72 hours (dose based on the IVPCA fentanyl trial that the patient had had earlier during this hospitalization). Hydromorphone 8-16 mg every 3 hours as needed was continued to manage breakthrough pain and withdrawal symptoms. On day 24, the patient was discharged on methadone and transdermal fentanyl, with the addition of meperidine IM and morphine IM, which the patient had used for many years, but now at lower doses and with longer intervals between administrations. At discharge, her pain score was 4/10 and the QTc interval

Dove inca.

False sense of safety by daily QTc interval monitoring

Table I Methadone dose over time and daily ECG

Day of IVPCA	Methadone			QTc interval
	Total methadone oral dose (mg/24 h)	IVPCA methadone dose (continuous rate plus demand, mg/24 h) and conversion to PO equivalency dose (IV to PO conversion factor = 2)	Total methadone dose in PO equivalent (mg/24 h)	duration (ms
Day I	40	28.8 × 2 = 57.6	97.6	449
Day 2	60	$58.8 \times 2 = 117.6$	177.6	445
Day 3	60	94.8 × 2 ≈ 189.6	249.6	430
Day 4	60	$151.6 \times 2 = 303.2$	363.2	
Day 5	60	$ 2! \times 2 = 242$	302	426
Day 6	60	$126.9 \times 2 = 253.8$	313,8	416
Day 7	60	$137.3 \times 2 = 274.6$	334	420
Day 8	60	$62 \times 2 = 124 (12 \text{ h})$	184	429
Day 9	20	02 × 2 = 124 (12 II)		317
Day 10	120	2	20 120	784
Ďay I I	120	_	120	476
Day 12	120	_	120	486
Day 13	120	<u> </u>	120	477
Day 14	120	val	120	495
Day 15	None	-	0	47 I 485
Day 16	None	_	0	432
Day 17	None	_	0	45 I
Day 18	None	-	o o	418
Day 19	None	발	0	437
Day 20	None	=	0	421
Day 21	30	-	30	404
Day 22	60	=	60	443
Day 23	90	=	90	448
Day 24	90	=	90	467

Notes: QTc duration versus total methadone dose. The first ECG was done to obtain a QTc interval duration baseline. Thereafter, daily ECGs were obtained to monitor the duration of the QTc while the IVPCA methadone titration was conducted. The total methadone dose was defined as the addition of the constant infusion rate, the demand dose, and the IV equivalent oral dose, in 24-hour periods. The methadone IV to oral conversion ratio was 1:2.

Abbreviations: ECG, electrocardiogram; IV, intravenous; PCA, patient-controlled analgesia; PO, per oral.

was 437 ms. We recognize that meperidine IM long-term use is not recommended, and the potential buildup of the metabolite normeperidine can cause seizures. However, the patient expressed anxiety at the prospect of discontinuing this medication, which she had been taking for many years without experiencing significant side effects. Therefore, we developed a plan to gradually switch from the use of injectable meperidine to injectable morphine, with eventual plan to transition to oral medications. After discharge, the patient was evaluated weekly in an outpatient setting for 1 month, at the end of which her pain score was 4/10, and the QTc interval was 372 ms. Four months later, the overall injectable mediations had been reduced by an additional 25% and her QTc interval duration was 410 ms.

#### **Discussion**

An ECG is a good screening tool for cardiac arrhythmias;<sup>14</sup> however, in this case, daily ECGs were not sufficient to guide

dosing during rapid methadone titration as a gradual prolongation of the QTc interval was not observed. Instead, the QTc interval jumped from what is considered to be low risk for cardiotoxicity to over 700 ms in less than 24 hours, putting the patient at high risk for fatal arrhythmias such as TdP. Since the methadone was preservative-free, and medications that can be substrates of the cytochrome P450 isoenzymes 3A4, 2D6, and 2B6, or those that can block the I,, were not initiated during this hospitalization, it is likely that the observed prolongation was due to a dose-dependent effect of methadone on the QTc interval caused by drug accumulation. In this report, daily ECGs did not detect a gradual increment of the QTc interval duration that would have guided clinical decisions to either decrease or stop the drug before the QTc interval exceeded 500 ms. Therefore, while daily ECGs may be useful, this should not be the only method used to guide clinical decisions regarding dose adjustments of methadone, as a normal QTc interval can give a false sense of safety.

Telemetry monitoring or ECG determinations every 12 hours should be considered in cases in which aggressive titration of IV methadone is elected. However, since methadone plasma levels were not measured in this case, the conclusions of this report cannot be generalized.

#### **Disclosure**

Ricardo A Cruciani is on the speaker board for ENDO, Covidien, and Pfizer; has been coinvestigator in research funded by Ameritox; has organized CME courses funded by Grupo Ferrer; and has been in the advisory board for Depomed and Janssen Pharmaceuticals. The authors report no other conflicts of interest in this work.

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County-lie   Cou		Marris Brown	- Interest	\$1,500 for 1 hour and 6 minutes of deposition (\$756/hr) ; \$400 for meeting with	Tommy Demas - Plaint Iff actorney	Provision, Marcy		FOR COLUMBIA COUNTY, FLORIDA	and the state of t	ᆫ
County   C		'	Stotefarm	\$1,000 for record implies. IMF, and IMF percent. \$1,000 for deposition.	Tomony Octobs - Plaintiff attorney	Bonesio, Genna		Circuit court of the third judicial droug, in and for Columbia	4611 NW 53 Ave, Gainesville, FL 32853	_
Ober 1 State Control of the War o	No	Jason Fancher	Statefarm	S1000 for the decoration and record review.	Tommy Domas - Plaintiff attorney	Staley, Randy		Creak court, third judicial circuit, in and for suwannee	136 SW Hassau Street, Lake City, FL	┸
Object   Constitute   Constitut		Westernie attorney/	Automos Sousians	or me reconstructurally	Tomory Demis - Plaintiff attorney	Budník, Anatoly	12-2012-000278-CA	Circuit yourt of the third ludicial circuit, in and for Columbia	4611 NW 53 Avg. Galnesville, FL 32853	
				nethic essectionations)	Retained by	Nume of client/petient	Cassell	Court style		ŝ



Hector Miranda-Grajales, M.D.

4201 Bee Caves Rd., Suite C-213 West Lake Hills, TX 78746 Tel: 512-960-4717 / Fax: 855-868-9882

Date: 7/17/19

In accordance to the rules for Federal Court, section (vi) statement of the compensation to be paid for the study and testimony in the case:

I billed and collected \$7,200 for the life care plan on Rose Hills. I will bill \$2,500 for a deposition lasting 4 hours or less and \$5,000 lasting more than 4 hours. I will bill \$5,000 for trial.

Hector Miranda-Grajales, M.D.



MIRS - Hector Miranda Grajales, MD 512-960-4717

4201 Bee Cave Rd West Lake Hills, Texas 78746 United States

Billied To

Julie L. Peschel Carlson Law Firm 2010 SW HK Dodgen Loop, Suite 201 Temple, TX 76504 Date of Issue

06/29/2019

Due Date 07/01/2019

Invoice Number

0000062

Amount Due (USD)

\$0.00

Description	Rate	Qty	Line Total
Hills, Rose - LCP with rush fee Hills, Rose - LCP with rush fee	\$7,200.00	1	\$7,200.00
	Subtotal Tax		7,200.00 0.00
	Total Amount Paid		7,200.00 7,200.00
	Amount Due (USD)		\$0.00